

EPA Registration File No. 74530-72



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

74530-72

Date of Issuance:

10/06/2016

REVISED

11/3/16

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Metolachlor TC

Name and Address of Registrant (include ZIP Code):

Helm Agro US, Inc.
4042 Park Oaks Blvd., Suite 330
Tampa, FL 33610

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

Signature of Approving Official:

Kathryn Montague, Product Manager 23
Herbicides Branch, Registration Division (7505P)

Date:

10/06/2016

REVISED 11/3/16

3. You are required to comply with the data requirements described in the DCI Order identified below:

- a. Metolachlor -GDCI-108801-1506

<https://www.regulations.gov/document?D=EPA-HQ-OPP-2014-0772-0024>

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts_prd.htm

4. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 74530-72."
5. Submit one copy of the revised final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 01/12/2016

If you have any questions, please contact Kathryn Montague by phone at 703-305-1243, or via email at montague.kathryn@epa.gov.

Enclosure



U.S. ENVIRONMENTAL PROTECTION AGENCY

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Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
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This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

Signature of Approving Official:

Kathryn Montague, Product Manager 23
Herbicides Branch, Registration Division (7505P)

Date:

10/6/16

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 74530-72."
4. Submit one copy of the revised final printed label for the record before you release the product for shipment.

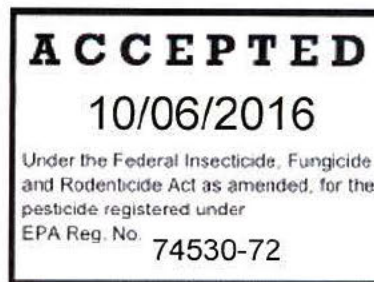
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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- Basic CSF dated 01/12/2016

If you have any questions, please contact Kathryn Montague by phone at 703-305-1243, or via email at montague.kathryn@epa.gov.

Enclosure



METOLACHLOR TC

Manufacturing Use Product for Formulating Use Only

ACTIVE INGREDIENT:

Metolachlor: 2-chloro-N-

(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide 98.3%

OTHER INGREDIENTS: 1.7%

TOTAL: 100.0%

EPA Registration No. 74530-xx

EPA Establishment No.: xxxx-xx-xxx

Net Contents: _____

KEEP OUT OF REACH OF CHILDREN CAUTION

| FIRST AID | |
|--|---|
| If on skin or clothing | <ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice. |
| If swallowed | <ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person. |
| HOT LINE NUMBER | |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For chemical emergency: Spill, leak, fire, exposure, or accident, call CHEMTREC 1-800-424-9300. | |

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes or clothing. Wear protective clothing (coveralls and gloves) when handling and using this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is to be used only for formulation into herbicides for the following use sites: Corn, Cotton, Peanuts, Pod crops, Potatoes, Safflowers, Sorghum (Grain and Forage), Soybeans, Tomatoes, Turf, Nursery stocks, Landscape plantings, and Established grasses grown for seed.

NOTE TO FORMULATORS: Formulators are responsible for providing data to support registration of products formulated from METOLACHLOR TC.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container. Do not contaminate with other pesticides.

PESTICIDE DISPOSAL: Open dumping is prohibited. Wastes resulting from the use of this product are toxic. Improper disposal of unused pesticide is a violation of federal law. Pesticide that cannot be used according to label instructions must be disposed of according to federal, state, or local procedures. For guidance in proper disposal methods, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office.

CONTAINER HANDLING: Refillable container. Refill this container with metolachlor only. Do not reuse this container for any other purpose. Thoroughly clean container before reuse. For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

Nonrefillable Container (rigid material; 5 gallons or greater): Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water: Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment, or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. Dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

CONDITIONS OF SALE

AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

Follow Directions for Use of this product carefully. It is impossible to eliminate all risks inherently

associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of Helm Agro US, Inc. or Seller. To the extent of applicable law, all such risks shall be assumed by Buyer and User, and Buyer and User agree to hold Helm and Seller harmless for any claims relating to such factors.

Helm warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Helm, and Buyer and User assume the risk of any such use. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, HELM MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

To the extent consistent with applicable law, in no event shall Helm or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF HELM AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF HELM OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

Helm and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of Helm.

Manufactured for:



HELM AGRO Inc.
401 E. Jackson St., Suite 1400
Tampa, FL 33602
info@helmagro.com

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

This Document Contains Confidential Information

Date: 07/15/16

SUBJECT: Product Chemistry of Metolachlor TC

FROM: Indira Gairola / Product Chemistry Team
CITAB/RD (7505P)

TO: Dominic Schuler / Kathryn Montague RM 23
Herbicide Branch / Registration Division (7505P)

DP BARCODE: 431017
DECISION No.: 511408
Registration No. / File Symbol No.: 74530-TE
PRODUCT NAME: Metolachlor TC
PC Code: 108801
REGISTRANT: Helm Agro US, Inc.
USE: Herbicide
FOOD USE: Yes [X] No []
MRID Numbers: 497812-01 to -05

INTRODUCTION:

The registrant has submitted an application for the registration of "Metolachlor TC" that will be produced by [REDACTED] Applicant is submitting a revised Basic CSF dated 07/12/16 (NC=98.3%) along with a revised label. Applicant claims the subject product to be similar to EPA Reg. #11603-43.

CITAB (Chemistry Team) has been asked to determine the acceptability of the aforementioned product chemistry data and CSF

SUMMARY OF FINDINGS:

1. Group A guidelines: 830.1550 (Product identity & composition) MRID #497812-01. Data for the identity and position of the product were provided. The active ingredient "of Metolachlor TC" is present at a nominal concentration of 98.3%. The product chemistry data submitted corresponding to Guideline 830.1550 satisfy the data requirements of 40CFR§158.320.

830.1600 (Description of materials used to produce the product) MRID#497812-01. The registrant provided a list of suppliers and MSDSs for the materials used to produce the product. The product chemistry data submitted corresponding to Guideline 830.1600 satisfy the data requirements of 40CFR§158.325.

830.1620 (Description of production process) MRID #497812-01. The production process by was described at the aforementioned site. The product chemistry data submitted corresponding to Guideline 830.1620 satisfy the data requirements of 40CFR§ 158.330

Manufacturing process information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

830.1670 (Discussion on the formation of impurities. 497812-02 A discussion of the origin and mechanism formation for the impurities in the product was provided. Applicant provided analyses of all process related impurities. The Analysis was performed using validated methods GC-FID. External standard quantitation methods were used to quantify the levels of a.i. and associated impurities. Detail analyses were included in the report. As per CITAB based on the level of impurities the impurities are not of significant potential toxicological health or environmental concern.

Data submitted corresponding to Guideline 830.1670 satisfy the data requirements of 40CFR§158.340.

830.1700 (Preliminary analysis) MRID 497812-02. Results of a five-batch preliminary analysis were provided. The average recovery content of a.i. for the source of manufacture ranged from 98.2%-98.3% with an average of 98.3%. These values are within the certified limits specified on the Basic CSF dated 01/12/16.

The product chemistry data submitted corresponding to Guideline 830.1700 satisfy the data requirements of 40CFR§158.345.1700

(Certified limits) CSFs dated 01/12/16. Certified limits were provided for the active ingredient, and upper certified limits were provided for the impurities in the product. Content of a.i. ranged from 98.3%-99.9% with an average of 98.8 %. The proposed upper limit is 99.9% and the lower limit is 95.4 %.

The product chemistry data submitted corresponding to Guideline 830.1750 satisfy the data requirements of 40CFR§158.350.

830.1800 (Enforcement analytical method) MRID #497812-02 submitted. A description of the enforcement analytical method and its validation were provided. The Analysis was performed using validated methods of HPLC, Content of the active ingredient was determined by High Performance Liquid Chromatography with Ultra Violet detection (HPLC-UV). Identity of the active ingredient was established by was established by Fourier Transform Infrared (FTIR) Spectrometry and Gas Chromatography Mass Spectrometry (GCMS), methods presented are accurate and precise for the determination of purity and analysis of impurities in ai. The analysis of the five lots of ai indicates an average 98.3% concentration of purity with [REDACTED] and [REDACTED] trace level impurities present at or above [REDACTED]. Average total closure of the five lots samples was reported.

The product chemistry data submitted corresponding to Guideline 830.1800 satisfy the data requirements of 40CFR§158.355.

For details please refer to the Confidential Appendix

2. Group B guidelines (physical-chemical properties) will be listed in the following pages.

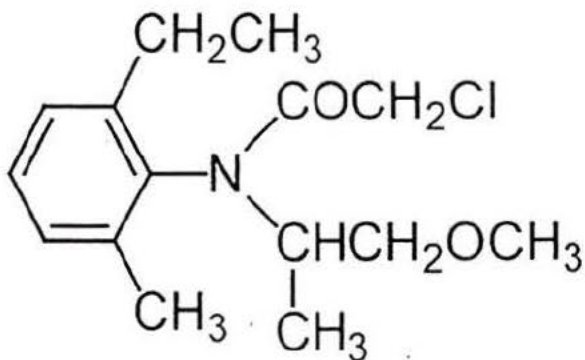
CONCLUSIONS:

The (CITAB/ Product Chemistry Team has reviewed the product chemistry data submitted for “of Metolachlor TC” and concluded:

1. All product chemistry data submitted for guideline 830 Series group A are acceptable.
2. The proposed Basic CSF (dated 01/12/16) is acceptable.
3. As per CITAB based on the level of impurities determined, the impurities are not of significant potential toxicological health or environmental concern.
Please refer to the Confidential Appendix and summary of findings for details.
4. Product chemistry data corresponding to 830 series group B (Physical-Chemical properties) are listed in the following pages. Data are determined acceptable
5. The subject product is considered to be substantially similar to EPA Reg. #11603-43 from chemistry point of view.

Identity

| | |
|------------------------|---|
| Trade Name: | Metolachlor TC |
| Alternate Brand Names: | N/A |
| EPA Registration No.: | 74530 – to be assigned |
| PC Code | 108801 |
| Source: | New technical Source: [REDACTED] |
| Common name (CAS): | 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide |
| Chemical Name (IUPAC): | 2-chloro-N-(6-ethyl-o-tolyl)-N-[(1RS)-2-methoxy-1-methylethyl]acetamide |
| Chemical Family: | benzoylcyclohexanedione herbicide (Group 27 Herbicide) |
| CAS Number | 51218-45-2 |
| Molecular Weight: | 283.80 |
| Identity Test: | Metolachlor, the active ingredient, is determined by High Performance Liquid Chromatography with Ultra Violet detection (HPLC-UV) |
| Empirical Formula: | C ₁₅ H ₂₂ ClNO ₂ |
| Structural Formula | |



| | |
|-----------------------|--|
| Isomeric Composition: | Racemic mixture of (1S)- and (1R)- isomers. |
| Purpose: | Herbicide for Formulation Purposes only |
| Mode of Action: | Metolachlor is applied before plants emerge. The product is absorbed |

Product ingredient source information may be entitled to confidential treatment

SUB GROUP B

Table 2: Physical and Chemical Properties of Metolachlor TC

| GLN | Requirement | MRID | Status | Result or Deficiency |
|----------|---|-----------|--------|---|
| 830.6302 | Color | 497812-03 | A | Yellow to light brown (Vol. 3 of 11) |
| 830.6303 | Physical state | 497812-03 | A | Clear liquid (Vol. 3 of 11) |
| 830.6304 | Odor | 497812-03 | A | Hydrocarbon-like (Vol. 3 of 11) |
| 830.6313 | Stability to normal and elevated temperatures, metals, and metal ions | 497812-01 | W | The product will not be packaged in metal containers (see applicant's letter dated 06/29/16). |
| 830.6314 | Oxidation/reduction; chemical incompatibility | 497812-03 | NA | Compatible with Water, 10% Monoammonium phosphate solution, Iron Powder, 10% Potassium permanganate solution, and Kerosene (Vol. 3 of 11) |
| 830.6315 | Flammability | 497812-01 | NA | Not flammable |
| 830.6316 | Explodability | 497812-01 | NA | The product does not present any explosive properties |
| 830.6317 | Storage stability | 497812-01 | I | The appropriate guideline study is being conducted |
| 830.6319 | Miscibility | 497812-01 | NA | Not required for MUP |
| 830.6320 | Corrosion characteristics | 497812-01 | A | The appropriate guideline study is being conducted. The product is not corrosive to plastic packaging (polyethylene or HDPE - containers are considered the preferred packaging material) |
| 830.7000 | pH | 497812-01 | A | 6.33 (1 % suspension in water; Vol. 3 of 11) Page 13 |
| 830.7050 | UV/Visible absorption | 497812-04 | A | See Note 1. Below |
| 830.7100 | Viscosity | 497812-01 | | |
| 830.7200 | Melting point | 497812-01 | NA | |
| 830.7220 | Boiling point | 497812-04 | A | >269°C (Vol. 4 of 11) |
| 830.7300 | Density | 497812-03 | A | 1,118 g/mL at 20°C; (Vol. 3 of 11) |
| 830.7550 | Octanol / water Partition coefficient | 497812-04 | A | logPow = 2.24 (Vol. 4 of 11) |
| 830.7950 | Vapor pressure | 497812-05 | A | 1.6x10 ⁻⁴ Pa at 25°C (Vol. 5 of 11) |
| 830.7840 | Water solubility | 497812-04 | A | Solubility in water = 0.5 g/L (Vol. 4 of 11) |
| 830.7370 | Dissociation constant | 497812-04 | A | No dissociation constant between pKa 2 and 10 ⁶ |

Note 1

| Solution | Neutral (pH 5.67) | | Acidic (pH 1.20) | | Alkaline (pH 12.62) | | |
|-----------------------------|-----------------------|---------|------------------------|---------|------------------------|---------|---------|
| Final Volume (mL) | 10 | | | | | | |
| Concentration (mol/L) | 8.60x10 ⁻⁴ | | 7.74 x10 ⁻⁴ | | 7.74 x10 ⁻⁴ | | |
| Wavelength of Maximum (nm) | 265.0 | 273.0 | 265.0 | 273.0 | 227.0 | 265.0 | 273.0 |
| Absorbance Observed (at nm) | 0.490 | 0.412 | 0.454 | 0.382 | 2.676 | 0.456 | 0.384 |
| ε Value calculated | 569.796 | 479.070 | 586.563 | 493.540 | 3457.364 | 589.147 | 496.124 |
| Band width calculated (nm) | 13.9 | 5.8 | 14.6 | 5.1 | 21.2 | 11.7 | 5.8 |



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WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

12/MAY/2016

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 74530-TE

Name of Pesticide Product: Metalochlor TC
EPA Reg. No.: 74530-TE
DP Barcode: 431018
Decision No.: 511408
Action Code: R333
PC Code: 108801 (metalochlor)

From: Eugenia McAndrew, Biologist *Eugenia McAndrew*

Through: John C. Redden, M.S., Senior Risk Assessor
Chemistry, Inerts and Toxicology Assessment Branch *JCR*
Registration Division (7505P)

To: Kathryn Montague, Risk Manager Team 23
Herbicide Branch
Registration Division (7505P)

Applicant: Helm Agro US, Inc.
4042 Park Oaks Blvd., Suite 330
Tampa, FL 33610

FORMULATION FROM LABEL:

| | |
|------------------------------|-----------------|
| <u>Active Ingredient(s):</u> | <u>% by wt.</u> |
| Metalochlor | 96.0 |
| <u>Other Ingredient(s):</u> | <u>4.0</u> |
| Total: | 100.0% |

ACTION REQUESTED: The Risk Manager requests a review of six acute toxicity studies submitted to support the registration of EPA File Symbol 74530-TE.

BACKGROUND: Helm Agro US, Inc. has submitted six acute toxicity studies (MRID Nos. 497812-06 to -11) to support the registration of Metolachlor TC, EPA File Symbol 74530-TE. The submission includes a label, a company letter and a basic CSF dated November 24, 2015 which must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

NOTE: These same studies with MRIDs 497253-04 to -09 were previously submitted for a different product. The studies were reviewed and classified as acceptable in a prior CITAB memo (McAndrew: D430165; EPA File Symbol 82633-ET; 07/APR/2016).

GLP: Yes

DEVIATIONS: None

LABELING: Based on the toxicity profile, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 74530-TE

PRODUCT NAME: Metolachlor TC

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment.

DATA EVALUATION RECORD

Product Reg. No.: 74530-TE

Product Name: Metalochlor Technical

1. DP BARCODE: 431018

2. PC CODE: 108801

3. CURRENT DATE: May 12, 2016

4. TEST MATERIAL: Metalochlor Technical (Batch # 101104026; purity 98.6%; pH 6.59; density 1.115 g/cm³; yellow transparent liquid)

*MRIDs 497253-04 to -09 were assigned to these same studies when they were originally reviewed by CITAB in a memo dated April 7, 2016

| Study/Species/Lab Study # /Date | MRID | Results | Tox Cat | Core Grade |
|--|---------------------------|--|------------|---------------|
| Acute oral toxicity / rat Intox Pvt. Ltd., Maharashtra, India/ Study #12250 April 17, 2012 OCSP 870.1100; OECD 425 | 49781206 49725304* | LD ₅₀ Females > 2000 mg/kg The test article was diluted in corn oil to obtain a concentration of 200 mg/ml. 5 animals were tested at the limit dose of 2000 mg/kg All animals survived and gained weight. No clinical signs of toxicity were observed. No gross pathological changes were noted at necropsy. | III | A |
| Acute dermal toxicity / rat Intox Pvt. Ltd., Maharashtra, India/ Study #12251 April 17, 2012 OCSP 870.1200; OECD 402 | 49781207 49725305* | LD ₅₀ > 2000 mg/kg (both sexes) All animals survived and gained weight. No clinical signs of toxicity or dermal irritation were observed. No gross pathological changes were noted at necropsy. | III | A |
| Acute inhalation toxicity / rat Intox Pvt. Ltd., Maharashtra, India/ Study #12252 April 17, 2012 OCSP 870.1300; OECD 403 | 49781208 49725306* | LC ₅₀ > 3.20 mg/L (both sexes) MMAD: 1.35 µm, 1.30 µm GSD: 2.85, 2.72 | IV | A |

| | | | | |
|---|---------------------------|---|----|---|
| | | All animals survived and gained weight. Clinical signs of toxicity included nasal discharge, abdominal breathing, hypoactivity and ruffled appearance which began during the exposure with recovery by day 2. No gross pathological changes were noted at necropsy. | | |
| Primary eye irritation / rabbit Intox Pvt. Ltd., Maharashtra, India Study #12254 April 17, 2012 OCSPP 870.2400; OECD 405 | 49781209 49725307* | 3 females tested No corneal opacity, iritis or positive scores for conjunctivitis were observed. The only irritation noted was conjunctival redness in all eyes at one hour (score of 1, not a positive effect). All eyes were free of irritation by 24 hours. | IV | A |
| Primary dermal irritation / rabbit Intox Pvt. Ltd., Maharashtra, India Study # 12253 April 17, 2012 OCSPP 870.2500; OECD 404 | 49781210 49725308* | PDI = 0.0 3 males tested No dermal irritation was observed at any of the treated sites. | IV | A |
| Dermal sensitization/guinea pig Intox Pvt. Ltd., Maharashtra, India Study #12255 April 17, 2012 OCSPP 870.2600; OECD 406 | 49781211 49725309* | Negative Results of historical positive control study are acceptable. | -- | A |

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap
W = Waived



Suzen



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D431017; **FILE SYMBOL No.:** 74530-TE (screen); **PRODUCT NAME:** Metolachlor TC;
DECISION No.: 511408; **PC Code(s):** 108801; **ACTION CODE:** R333; **FOOD Use:** Yes

DATE OUT: January 11, 2016

SUBJECT: 45/90 day screen results for technical product "Metolachlor TC"

FROM: Shyam Mathur,
Product Chemistry Team Leader
CITAB/RD (7505P)

SBM

TO: Dominic Schuler / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

Company Name: Helm Agro US Incorporation
Active Ingredient(s): Metolachlor (98.3%)
MRID Nos: submitted – 49781201 to 49781205

CONCLUSION:

Deficiencies: Yes

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

Group A: All required data submitted

Group B: All required data submitted

CSF: Basic CSF submitted (dated 11-24-2015)

Note 1: The nominal concentration of the AI Metolachlor must be changed to 98.3% as has been determined by 5 batch analysis.

Draft Label: Submitted

Note to PM: The registrant is recommended to revise the Ingredient statement on the product label to indicate correct nominal concentration of the AI as 98.3% and not 96%.

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to author of this report the corrected deficiencies in response to 10 day letter. The corrected information will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

Bert Volger

From: notification@pay.gov
Sent: Monday, November 23, 2015 11:02 AM
To: bertvolger@ceresinternational.com
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25OHMSRE
Agency Tracking ID: 74912074798
Transaction Type: Sale
Transaction Date: 11/23/2015 11:02:11 AM EST

Account Holder Name: Bert Volger

Transaction Amount: \$19,838.00
Card Type: Visa
Card Number: *****9191

Registration Number:
Company Name: Helm Agro US, Inc.
Company Number: 74530
Action Code: R333

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



United States
Environmental Protection Agency
Washington, DC 20460

☒ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|--|--|--|
| 1. Company/Product Number 74530-xx | 2. EPA Product Manager Kathryn Montague | 3. Proposed Classification |
| 4. Company/Product (Name) Helm Agro US, Inc. /Metolachlor TC | PM# PM 23 | <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 5. Name and Address of Application (Include ZIP Code) Helm Agro US, Inc. 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610 <input type="checkbox"/> Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: Technical Metolachlor II (EPA Reg. No. 11603-43) | |

Section - II

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input checked="" type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Explain below. |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Application for a "me-too" registration of a new manufacturing use product, Metolachlor TC, with an unregistered source of active ingredient that requires reviews of product chemistry and acute toxicity data (Non-fast track; PRIA EPA # R333, EPA decision review time of 10 months, fee = \$19,838);
EMAIL: bertvolger@ceresinternational.com

Section - III

| | | | |
|--|---|--|--|
| 1. Material This Product Will Be Packaged In: | | | |
| Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | 2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____ |
| * Certification must be submitted | | If "Yes", Unit Packaging wgt. No. per container | If "Yes" Package wgt. No. per container |
| 3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container | 5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product |
| 6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | | |

Section - IV

| | | | |
|---|--|---|--|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | |
| Name Bert Volger | Title Agent for HELM Agro US, Inc. | Telephone No. (Include Area Code) Phone: (610) 793-3222 Fax: (610) 200-5576 | |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | 6. Date Application Received (Stamped) |
| 2. Signature | 3. Title Agent for Helm Agro US, Inc. | | |
| 4. Typed Name Bert Volger | 5. Date November 24, 2015 | | |



Ceres International LLC

Via Courier Delivery

November 24, 2015

U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Ms. Kathryn Montague
Registration Manager (PM – 23)

Subject: Metolachlor TC (EPA-Reg.No.74530 - to be assigned)
Application for new product registration

Dear Ms. Montague:

HELM Agro US Inc. herewith submits an application for a new “me-too” registration of an existing active ingredient, metolachlor, being used solely for the formulation into registered end-use herbicide products for terrestrial food and non-crop uses. Metolachlor TC is very similar to the existing registration of ADAMA Agan’s Technical Metolachlor II (EPA Reg. No. 11603-43).

The subject application for registration is supported by the enclosed Product Chemistry data (Volume 1 to 5 of 11), the enclosed Acute Toxicity data package (Volume 6 to 11 of 11; see attached bibliography of submitted studies), and the cited metolachlor data base of submitted studies (see enclosed Data Matrix, and Citation of Data).

The proposed labeling is based on the results of the enclosed Acute Toxicity data (see also toxicity summary below), following EPA’s Label Review Manual and 40 CFR Part 156.

This application is subject to PRIA 3 - Category R333: New MUP containing unregistered source of active ingredient; requires science data review; selective data citation; decision time 10 months; fee \$19,838.-

In order to facilitate the subject application, enclosed you will find the following information/ administrative materials:

1. EPA Form 8570-1:
An executed "Application for Pesticide Registration".
2. Bibliography of Submitted Studies
One copy of the Bibliography of Submitted Studies is enclosed. This provides an index of study titles and references to EPA Data Requirements by OPPTS Guideline Number.
3. Proposed Label
Five copies of the proposed Metolachlor TC label are enclosed.
4. Acute Toxicity Data
The results of the acute toxicity studies for Metolachlor TC are based on the results from the submitted studies (OPP Guideline Ref. # 81-1 to 81-6). The results show that Metolachlor TC has low acute oral and dermal toxicity (Cat. III), very low inhalation toxicity (Cat.IV), and is minimally irritating to the eye (Cat IV). The product is not irritating to the skin (Cat. IV), and is not a skin sensitizer (negative) in the guinea pig. Based on the results of these studies, Metolachlor TC is classified as a Toxicity Category III product with the Signal word, "CAUTION" (see proposed labeling).

Acute Toxicity Data for Metolachlor TC (Summary)

| OPPTS Guideline # | Study | Results | Category |
|-------------------|----------------------------------|---|----------|
| 870.1100 | LD50 Oral - rat | > 2,000 mg/kg | III |
| 870.1200 | LD50 Dermal - rat | > 2,000 mg/kg | III |
| 870.1300 | LC50 4h Inhalation - rat | >3.20 mg/l | IV |
| 870-2400 | Eye Irritation rabbit | Minimally – irritating (clearing in less than 24 hours) | IV |
| 870-2500 | Skin Irritation rabbit | Non - irritating | IV |
| 870.2600 | Skin Sensitization Guinea Pig | Negative | N/A |

5. Confidential Statement of Formula
One copy of the Confidential Statement of Formula (CSF) is enclosed.
6. Study Data
Three copies of each study report (total of 11 volumes) have been enclosed.
7. Certification with Respect to Citation of Generic Data
An executed EPA form 8570-34 with respect to citation of data has been enclosed.
8. Data Matrix (EPA form 8570-35)
One copy of the metolachlor Data Matrix (Agency Internal Use, and Public Use - one copy each); listing of submitted data and the individual data submitter per EPA's Data Submitters list as of July 1, 2015.
9. PRIA fee payment
Copy of payment confirmation is enclosed;
(e-mail – Agency Tracking ID 74912074798).

If you need any additional technical information or assistance regarding this application, please do not hesitate to contact me at 610-793-3222 (bertvolger@ceresinternational.com).

Sincerely,



Bert Volger, Ph.D.
Agent for
HELM Agro US, Inc.

Cc: Jan Stechmann - HAI

Enclosure

BIBLIOGRAPHY OF SUBMITTED STUDIES

Name and Address of Submitter: Helm Agro US, Inc.
4042 Park Oaks Blvd., Suite 330
Tampa, FL 33610

Product(s): Metolachlor TC

EPA Registration No: 74530-to be assigned

Purpose of Submission: Submission of data in support of the application for “me-too” registration of Metolachlor TC

Date of Submission: November 24, 2015

| Volume Number | Study Title | Laboratory, ID Number | OPPTS Guideline Reference Number | EPA MRID Number (Reserved for EPA Use) |
|---------------|--|--|--|---|
| 1 of 11 | Metolachlor TC Product Identity and Composition Description of Materials Used Description of Production Process Discussion of the Formation of Impurities Certified Limits Enforcement Analytical Method Submittal of Sample Physical and Chemical Properties (Subpart B) | Ceres #151120 | 830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800 & 830.1900, 830.6302- 7950 | |
| 2 of 11 | Metolachlor TC Determination of Active Content and Impurity Profile of Metolachlor (Five-Batch Analysis) | AgriFor Scientific Pty, Ltd. #BT-010 | 830.1700, 830.1800 | |
| 3 of 11 | Metolachlor TC (Helm Sample No.37-15/0099) Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, and Density/Bulk Density | Product Safety Labs #41252 | 830.6302, 830.6303, 830.6304, 830.6314, 830.7000, 830.7300 | |

| Volume Number | Study Title | Laboratory, ID Number | OPPTS Guideline Reference Number | EPA MRID Number (Reserved for EPA Use) |
|----------------------|--|-------------------------------|--|---|
| 4 of 11 | Metolachlor TC (Helm Sample No.37-15/0099) Physical and Chemical Characteristics: UV/Visible Absorption, Boiling Point, Dissociation Constant, Partition Coefficient, and Water Solubility | Product Safety Labs #41253 | 830.7050, 830.7220, 830.7370, 830.7550, 830.7840 | |
| 5 of 11 | Metolachlor TC Vapour Pressure | Envigo CRS Ltd. #MIB0048 | 830.7950 | |
| 6 of 11 | Metolachlor TC Acute Oral Toxicity Study of Metolachlor Technical In Rats | INTOX PVT. Ltd. #12250 | 870.1100 | |
| 7 of 11 | Metolachlor TC Acute Dermal Toxicity Study of Metolachlor Technical In Rats | INTOX PVT. Ltd. #12251 | 870.1200 | |
| 8 of 11 | Metolachlor TC Acute Inhalation Toxicity Study of Metolachlor Technical In Rats | INTOX PVT. Ltd. #12252 | 870.1300 | |
| 9 of 11 | Metolachlor TC Acute Eye Irritation/Corrosion Study of Metolachlor Technical In Rabbit | INTOX PVT. Ltd. #12254 | 870.2400 | |
| 10 of 11 | Metolachlor TC Acute Dermal Irritation/Corrosion Study of Metolachlor Technical in Rabbit | INTOX PVT. Ltd. #12253 | 870.2500 | |
| 11 of 11 | Metolachlor TC Skin Sensitization Study (Buehler Test) of Metolachlor Technical in Guinea Pigs | INTOX PVT. Ltd. #12255 | 870.2600 | |



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401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

| | |
|---|---|
| Applicant's/Registrant's Name, Address, and Telephone Number Helm Agro US, Inc., 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610 | EPA Registration Number/File Symbol 74530 - xx |
| Active Ingredient(s) and/or representative test compound(s) Metolachlor | Date November 24, 2015 |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food and Non-Crop Uses | Product Name Metolachlor TC |

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

| | |
|--|---|
| <input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). | <input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used). |
|--|---|

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Bert Volger

Date

11-24-2015

Typed or Printed Name and Title

Bert Volger, Agent for Helm Agro US, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

| Date: 11/24/2015 | | EPA Reg. No./File Symbol: 74530-xx | | Page 1 of 4 | |
|---|---|------------------------------------|--------------------|-------------|---------------------------------|
| Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610 | | Product: Metolachlor TC | | | |
| Ingredient: Metolachlor | | | | | |
| Guideline Reference Numbers, OPP/OPPTS | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 61-1/ 830.1550 | Product Identity and Composition | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 61-2/ 830.1600 & 830.1620 | Beginning Materials and Manufacturing Process | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 61-3/ 830.1670 | Discussion of the Formation of Impurities | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 62-1/ 830.1700 | Preliminary Analysis | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 62-2/ 830.1750 | Certified Limits | N/A | Helm Agro US, Inc. | OWN | See submitted CSF |
| 62-3/ 830.1800 | Enforcement Analytical Method | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 63-2/ 830.6302 | Color | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 63-3/ 830.6303 | Physical State | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 63-4/ 830.6304 | Odor | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 63-6/ 830.7220 | Boiling Point | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 63-7/ 830.7300 | Density | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |

EPA Form 8570-35 (9-97)

Agency Internal Use Copy



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401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

| Date: 11/24/2015 | | EPA Reg. No./File Symbol: 74530-xx | | Page 2 of 4 | |
|---|---|------------------------------------|--------------------|-------------|--|
| Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610 | | Product: Metolachlor TC | | | |
| Ingredient: Metolachlor | | | | | |
| Guideline Reference Numbers, OPP/OPPTS | Guideline Study Name | MRID Number | Submitter | Status | Note |
| 63-8/ 830.7840 | Solubility | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 63-10/ 830.7370 | Dissociation Constant | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 63-11/ 830.7550 | Octanol/Water Partition Coefficient | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 63-12/ 830.7000 | pH | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 63-14/ 830.6314 | Oxidation/reduction: Chemical incompatibility | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 63.15/ 830.6315 | Flammability | | | | Not flammable (Melting Point far above 40°C); not required |
| 63-16/ 830.6316 | Explosibility | | | | The product does not present any explosive properties |
| 63-17/ 830.6317 | Storage Stability | | | | Study is being conducted. |
| 63-20/ 830.6320 | Corrosion Characteristics | | | | Study is being conducted. |
| N/A/ 330.7050 | UV visible light absorption | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |

EPA Form 3570-35 (9-97)

Agency Internal Use Copy



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Form Approved OMB No. 2070-0060

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DATA MATRIX

| | | |
|---|------------------------------------|-------------|
| Date: 11/24/2015 | EPA Reg. No./File Symbol: 74530-xx | Page 3 of 4 |
| Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610 | Product: Metolachlor TC | |

Ingredient: Metolachlor

| Guideline Reference Numbers, OPP/OPPTS | Guideline Study Name | MRID Number | Submitter | Status | Note |
|--|-------------------------------------|----------------|--------------------|--------|---------------------------------|
| 81-1/ 870.1100 | Acute Oral Toxicity - Rat | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 81-2/ 870.1200 | Acute Dermal Toxicity-Rabbit | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 81-3/ 870.1300 | Acute Inhalation Toxicity-Rat | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 81-4/ 870.2400 | Primary Eye Irritation-Rabbit | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 81-5/ 870.2500 | Primary Dermal Irritation-Rabbit | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |
| 81-6/ 870.2600 | Dermal Sensitization in Guinea Pigs | To be assigned | Helm Agro US, Inc. | OWN | Submitted with this application |

GENERIC DATA

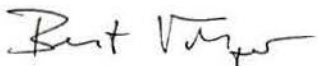
| | | | | | |
|--|--|----------------|-------------------------|-----|--|
| | Helm Agro US Inc. is making offers-to-pay to the following companies listed on EPA's Data Submitters list as of July 1, 2015 | Company Number | | | |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 100 | Syngenta | PAY | |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 352 | E.I. DuPont | PAY | |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 11603 | ADAMA Agan | PAY | |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 11678 | Adama Makhteshim Ltd. | PAY | |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 19713 | Drexel Chemical Co. | PAY | |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 34704 | Loveland Products, Inc. | PAY | |



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WASHINGTON, D.C. 20460

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DATA MATRIX

| Date: 11/24/2015 | | EPA Reg. No./File Symbol: 74530-xx | | Page 4 of 4 | |
|---|---|------------------------------------|---|-------------|------------------|
| Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 4042 Park Oaks Blvd., Suite 330 Tampa, FL 33610 | | Product: Metolachlor TC | | | |
| Ingredient: Metolachlor | | | | | |
| Guideline Reference Numbers, OPP/OPPTS | Guideline Study Name | Company Number | Submitter | Status | Note |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 42750 | Albaugh, LLC | PAY | |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 56077 | Cedar Chemical Corp. | PAY | |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 60063 | Sipcam Agro USA, Inc. | PAY | |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 66222 | Makhteshim Agan of North America | PAY | |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 66607 | Spray Drift Task Force | OWN | Member of SDTF |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 67760 | Cheminova, Inc. | PAY | |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 71754 | Outdoor Residential Exposure Task Force | OWN | Member of ORTF |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 71755 | Agricultural Reentry Task Force | OWN | Member of ARTF |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 75008 | Metolachlor Task Force | PAY | |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 75234 | Agricultural Handler Exposure Task Force | OWN | Member of AHETF |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 84653 | Generic Endangered Species Task Force | OWN | Member of GESTF |
| | Cite-All under Selective Method utilized by Helm Agro US Inc. | 89168 | Liberty Crop Protection, LLC | PAY | |
| Signature:  | | | Name and Title: Bert Volger, Ph.D. Agent for HELM AGRO US Inc. | | Date: 11/24/2015 |

